

**K991386 EARLY OVULATION PREDICTOR (STICK), ONE STEP  
OVULATION PREDICTOR (STICK), OVULATION PREDICTOR  
(STICK)**May 25, 1999  
34 days to decisionK991386 · Product code: **CEP** · Chemistry  
Source: <https://www.510kdatabase.net/k991386/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Apr 21, 1999
Decision date	May 25, 1999
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Selfcare, Inc.</b>
Location	Waltham, MA, US
Contact	Carol Adiletto
510(k) history	15 submissions · 15 cleared · 1996-2000

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